

REMARKS

In the amendments above, Clams 1 to 12 have been cancelled in favor of newly added Claims 13 to 27, to more particularly point out and distinctly claim Applicant's invention. Support for newly added Claims 13 to 27 can be found, for example, as follows:

<u>CLAIM</u>	<u>SUPPORT</u>
13	Claim 1
14	Claim 3
15	Claim 8
16	Claim 4
17	Claim 5
18	Claim 5
19	Claim 5
20	Claim 5
21	Claim 6
22	Claim 6
23	Claim 12
24	Claims 1 and 5
25	Claim 3

26	Claim 4
27	Claim 5

No new matter has been added. Entry and consideration of the amendments and following remarks is respectfully requested.

REJECTION UNDER 35 U.S.C. § 103(a)

Claims 1 and 3-12 have been rejected under 35 U.S.C. § 103(a) as being obvious over Riitano et al., U.S. Patent No. 6,575,747 ("Riitano"). The Examiner maintains that Riitano discloses a root canal instrument with a metallic needle part and a substantially continuous gripping end, which can be gripped by the fingers, of homogeneous structure; that the handle can be made of deformable plastic material such that the coefficient of friction is much higher than that of metal; that there is also an embodiment where the gripping end has a surface layer and there is a layer underneath the surface layer; that since the file part of Riitano's instrument is made from strong resilient metal and the handle is made from deformable material, it is inherent that the surface layer material of the handle has a lower hardness than that of the underneath layer, since it is continuous with the metallic needle part; that Riitano does not disclose the ranges of coefficient of kinetic friction or Shore hardness of the layers of the gripping end that are claimed; that, however, it would have been obvious to one having ordinary skill in the art to manufacture the root canal instrument within the specifically claimed ranges of the coefficient of kinetic friction and Shore hardness, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art; that Riitano discloses the fact that a plastic material is used on the handle to be deformable and have a higher coefficient of kinetic coefficient than that of metal; and that, therefore, a teaching exists to modify these

specific variables to obtain a handle that has the ideal hardness and coefficient of kinetic friction.

Applicant respectfully traverses the rejection since Riitano neither discloses nor suggests the claimed invention.

The invention described and claimed herein concerns a root canal instrument having a metallic needle part and a gripping end attached to the upper end of the needle part, for manual root canal procedures. The gripping end has an outer surface that is substantially continuous and that has a coefficient of friction that is greater than 0.4, determined as a coefficient of kinetic friction with steel as a material pair. The hardness and thickness of the outer surface of the gripping end are chosen so that the shape of the gripping end is recoverably deformable from a force applied by gripping fingers of a user. The instrument of the invention is tool to be used manually.

Riitano discloses a dental instrument or piece that is designed and intended for, and only useful with, the chuck of a powered endodontic instrument. This dental piece comprises a metal file and a handle, which handle could comprise metal or certain plastics. Riitano distinguishes the claimed dental piece from the manual instruments identified in, for example, Figures 1 and 2 of Riitano.

While the Examiner is correct that there are some teachings in Riitano that are superficially applicable to Applicant's invention, a fundamental flaw in the Examiner's reasoning is that he essentially equates the dental piece disclosed and claimed by Riitano with the manual dental instrument that is Applicant's invention. They are NOT the same, as even Riitano recognizes. With regard to this, for example, a man skilled in the art is already instinctively aware that the manual instruments as described and claimed herein have larger diameters than those designed to be used via dental handpieces, so he or she would immediately realize that a needle according to the current invention would not fit in the chuck of Riitano's endodontic instrument, and that Riitano's dental piece could not function as a manual instrument for a root canal procedure since it would be too small to

be held by a user. Further, as will be discussed in more detail below, in addition to the size problem, Riitano's instrument would have just the problems related to gripping and use of the instrument by fingertips the current invention is designed to overcome.

As disclosed in Applicant's specification, the handle of the claimed invention has been carefully designed to have a material that has a combination of a sufficiently high coefficient of friction, hardness, and deformability in an elastomer of enough thickness to enable a user to grasp and use the claimed instrument effectively with minimum fatigue. This is not a question of optimizing values that may have been previously disclosed. Instead, the Applicant has found certain characteristics that work for the intended purpose, namely, manual root canal procedures, that are not taught or suggested by Riitano's invention.

More particularly, the Examiner maintains that the general teachings of Riitano are sufficient to constitute motivation to modify Riitano to have the optimal or workable ranges recited in the claimed invention. Specifically, the Examiner states that Riitano discloses a handle made out of deformable plastic having a higher coefficient of friction than metal. Purportedly this disclosure is sufficient to provide a suggestion and motivation to modify Riitano to have a handle with a coefficient of friction higher than 0.4 and a hardness and thickness whose shape is recoverably deformable from a force applied by gripping fingers. In fact, however, Riitano does not give proper support for such a position, as also will be discussed in even more detail below.

A further flaw in the Examiner's application of Riitano is that there is no teaching or suggestion whatsoever in Riitano that the plastic handle be *recoverably* deformable. Riitano simply suggests a means for locking the handle in a latchless chuck. The solution proposed by Riitano is that the retention arms of the chuck press into the deformable handle to grasp it. There is no indication that when the handle is removed from the chuck the handle recovers its original shape. The Examiner's assertion that he "believes that the

recovery reformation is inherent and essential ...” is unsupported and therefore improper. An unsupported belief should not be used as a basis of a rejection.

The comments above are already sufficient to show that Riitano does not disclose or suggest Applicant’s invention. However, Applicant wants to clarify the record regarding coefficients of friction. More particularly, Riitano cannot be read to disclose that the plastic material itself used in the handle has greater coefficient of friction than metal. This would be highly unlikely since plastics generally have a lower coefficient of friction than metals. One skilled in the art would understand the disclosure of Riitano to be referring to hard plastics that include a deformation (especially those having a coefficient of friction typical to plastics used in the root canal needles at the time of Riitano’s invention, such as polyphenylene sulphide).

The Examiner's reliance on Column 16, lines 41-47, of Riitano is misplaced. Riitano comments that the material of handle 12 provides "greater friction." In context, Riitano suggests that when the retention arms press into and deform handle 12, the overall effect is to press the retention arms into the handle thereby creating friction by locking the retention arms in the handle. Riitano does *not* suggest that the plastic material itself would have a high coefficient of friction, but rather that the construction as a whole would create high "friction" or actually provide a good grip. This contrasts with the invention claimed here where the outer surface material of the gripping end as such has a high coefficient of friction, regardless of whether there is any deformation or not.

As discussed in the description of the instant application, the prior art gripping ends that were designed to be used by fingers include various formulations on the surface of their handles to increase friction between the fingers and the handle. Riitano is no different. Rather than rely on the coefficient of friction of the material itself, as does the claimed invention, Riitano suggests deforming the handle to produce a groove whereby the grip to the handle may be increased. The claimed invention is an improvement over and distinguished from the prior art references and Riitano by reciting a material used on

the outer surface of the gripping end that itself has a substantially continuous surface and a high coefficient of friction, without the need for protrusions, crevices, or other deformations. Accordingly, Riitano does not teach or suggest an outer surface *material* of the gripping end having a coefficient of friction higher than 0.4.

Applicant reiterates that the Riitano dental piece cannot be modified as proposed by the Examiner. It is well established that there can be no suggestion to modify a prior art reference if the modification would render the prior art unsatisfactory for its intended purpose. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). (See also MPEP 2143.01(v)). In contrast to the handle of the manual root canal instrument claimed herein, the handle of the Riitano dental piece is intended to be held by a chuck of a dental endodontic instrument or handpiece, not to be held between fingers of a user. Because of this fundamental difference, the Riitano dental piece cannot be modified to have a handle that is soft enough to be recoverably deformable from a force applied by fingers of a user. In fact, if a Riitano dental piece was modified so that the handle of the instrument was as soft as the gripping end of the manual root canal instrument claimed here, the Riitano dental piece would cease to function properly because the file would be too unstable between the retention arms of the chuck.

The incompatibility of a soft gripping end with the Riitano dental piece is even more pronounced when dealing with handpieces that rotate the file at high revolution speeds. A modified handle of Riitano's dental piece that is recoverably deformable between gripping fingers would be too wobbly and dangerous to use for such an intended purpose. Accordingly, there is no motivation or suggestion to modify Riitano to arrive at the claimed invention.

Thus, one of ordinary skill in the art at the time the invention was made would interpret the cited portion of Riitano, pertaining to a handle made of deformable plastic, as referring to plastics that are much harder (and more slippery) than the claimed materials that are deformable between fingers. An example of such plastics referred to

by Riitano is polyphenylene sulphide. This material would have been used because it can endure thermal and chemical disinfection required in the context of use of these kinds of instruments, and, in fact, such a material was referred to as prior art in the description of the current application as well. However, such plastics could certainly not be recoverably deformable between gripping fingers of a user, as claimed, nor would they have the claimed coefficient of friction. No mention is made in Riitano of a recoverably deformable material by a force applied by the gripping fingers; nor could there have been since it would have rendered the invention unsuitable for its intended purpose. Furthermore, the *material* of the handle of Riitano also lacks the coefficient of friction recited in the claims here.

In view of the above, it is respectfully submitted that Riitano does not teach or suggest the invention claimed herein. Accordingly, Claim 13 and the claims dependent thereon are patentable.

Claims 17 to 20 are further distinguishable over Riitano because they recite that the gripping end, or its outer layer, is made of an elastomer having a hardness in the range of about 10 to about 95 Shore A. A number of silicone materials are examples of a material that does have this property. This range is not disclosed by a general reference to plastics, and the reference to plastics does not suggest a material with a hardness in the recited ranges. The vast majority of plastics have a hardness above the recited range. Furthermore, even if plastics exist that fall within the claimed range, the disclosure in the reference was not made with sufficient specificity to teach, suggest, or motivate one skilled in the art to choose a material in this range.

One last point: When the Examiner argues, e.g., that a teaching exists to obtain a handle with “ideal hardness and coefficient of kinetic friction”, how would a man skilled in the art know what would be the context of the “ideal” whereto he should aim for to begin with? The current invention is a combination of a number of features, and the prior art does not give any indication towards taking specifically the claimed features under

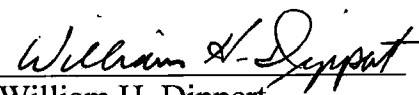
consideration in the first place. The current invention is based on taking a completely new approach in the design of a novel handle for a root canal instrument by dropping the general teaching of the prior art of using various kinds of physical forms on the surface layer of the handle, to provide better “friction” (grip) for the fingers upon use of the instrument. Instead, the handle according to this new approach is arranged to have a substantially continuous outer surface, and the necessary “usability” of the instrument is the achieved by the combination of the other claimed features.

In view of the arguments presented above, it is submitted that the Examiner’s rejections have been overcome and should be withdrawn. The application should now be in condition for allowance.

Should any changes to the claims and/or specification be deemed necessary to place the application in condition for allowance, the Examiner is respectfully requested to contact the undersigned to discuss the same.

Reconsideration and allowance of the claims here are respectfully requested.

Respectfully submitted,
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